UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

FERRING PHARMACEUTICALS INC., FERRING B.V., and FERRING INTERNATIONAL CENTER S.A., Plaintiffs, v. SERENITY PHARMACEUTICALS, LLC, and REPRISE BIOPHARMACEUTICS, LLC, Defendants.	C.A. No. 1:17-cv-09922 (RWS) ECF Case
SERENITY PHARMACEUTICALS, LLC, REPRISE BIOPHARMACEUTICS, LLC, and AVADEL SPECIALTY PHARMACEUTICALS, LLC, Counterclaim-Plaintiffs, -v- FERRING B.V., FERRING INTERNATIONAL CENTER S.A., and FERRING PHARMACEUTICALS INC., Counterclaim-Defendants.	C.A. No. 1:17-cv-09922 (RWS) ECF Case

PLAINTIFFS' REPLY TO COUNTERCLAIMS AND AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS IN REPLY

Plaintiffs Ferring Pharmaceuticals Inc. ("Ferring Pharma"), Ferring B.V., and Ferring International Center S.A. ("FICSA"), (collectively, "Ferring") hereby reply to the Counterclaims of Counterclaimants Serenity Pharmaceuticals, LLC ("Serenity"), Reprise Biopharmaceutics,

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LLC ("Reprise") and Avadel Specialty Pharmaceuticals, LLC ("Avadel"), (collectively "Counterclaimants") as follows:

NATURE OF THE SUIT

1. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Ferring states this action arises under the Patent Laws of the United States, 35 U.S.C. et seq. and that this paragraph purports to describe counterclaims for patent infringement and related claims, as well as claims for declaratory judgment of non-infringement arising under the trademark laws of the United States. Ferring admits that this action relates to Ferring's NOCDURNA (desmopressin acetate) sublingual tablets. Ferring denies the remaining allegations in paragraph 1.

2. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Ferring denies that it has infringed any claims of the '203 or '321 patents and therefore has not willfully infringed the '203 or '321 patents. Ferring denies that Counterclaimants' use of the *NOCTIVA* mark does not infringe any rights of Ferring. Ferring states that Counterclaimants are not entitled to any relief, including any judgment sought. Ferring denies the remaining allegations in paragraph 2.

THE PARTIES

3. On information and belief, admitted.

4. Ferring lacks sufficient information to establish the accuracy of the allegations in this paragraph. Accordingly, Ferring denies the allegations in paragraph 4.

5. Ferring lacks sufficient information to establish the accuracy of the allegations in this paragraph. Accordingly, Ferring denies the allegations in paragraph 5.

6. On information and belief, admitted.

7. This paragraph states a legal conclusion to which no response is required. On information and belief, Ferring admits that Dr. Fein assigned the '203 and '321 patents to Reprise. Ferring lacks sufficient information to establish the accuracy of the remaining allegations in this paragraph. Accordingly, Ferring denies the remaining allegations in paragraph 7.

8. On information and belief, admitted.

9. Ferring lacks sufficient information to establish the accuracy of the allegations in this paragraph. Accordingly, Ferring denies the allegations in paragraph 9.

10. Ferring lacks sufficient information to establish the accuracy of the allegations in this paragraph. Accordingly, Ferring denies the allegations in paragraph 10.

11. Admitted.

12. Admitted.

13. Admitted.

14. Admitted.

15. Ferring admits that Ferring Pharmaceuticals Inc. is a private corporation organized under the laws of the State of Delaware, having its principal place of business at 100 Interpace Parkway, Parsippany, New Jersey 07054. Ferring admits that Ferring Pharmaceuticals Inc. formerly had its principal place of business in Tarrytown, New York. Ferring denies the remaining allegations in paragraph 15.

16. Admitted.

17. Admitted.

JURISDICTION AND VENUE

18. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Ferring states the Answer includes counterclaims that purport to arise under the Patent Laws of the United States, 35 U.S.C. et seq. and the trademark laws of the United States, Title 15, United States Code. Ferring admits that this court has subject matter jurisdiction over this action. Ferring denies the remaining allegations in paragraph 18.

19. Ferring admits that it will not contest personal jurisdiction over Ferring for purposes of this action only and that Ferring has asserted claims against Serenity and Reprise in this District in Action No. 12-cv-2650 (RWS). Ferring denies the remaining allegations in paragraph 19.

20. Ferring admits that it will not contest personal jurisdiction over Ferring for purposes of this action only and that Ferring markets and sells drug products throughout the United States and in the Southern District of New York. Ferring denies the remaining allegations in paragraph 20.

21. Ferring denies that venue is proper for this action under *TC Heartland LLC v. Kraft Foods Group Brands LLC*, 137 S.Ct. 1514 (2017) and denies any remaining allegations in paragraph 21.

22. Ferring denies that venue is proper for this action under *TC Heartland LLC v. Kraft Foods Group Brands LLC*, 137 S.Ct. 1514 (2017) and denies any remaining allegations in paragraph 22.

THE ASSERTED PATENTS

THE '203 PATENT

23. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Ferring admits that the '203 patent issued on July 29, 2008, names Seymour Fein as its sole inventor, is titled "PHARMACEUTICAL COMPOSITIONS INCLUDING LOW DOSAGES OF DESMOPRESSIN," and is listed in the Orange Book as purportedly covering *NOCTIVA*. Ferring also admits that *NOCTIVA* is the subject of approved NDA No. 201656. Ferring denies that '203 patent was duly and legally issued and states that it is invalid and unenforceable. Ferring lacks sufficient information to establish the accuracy of whether Serenity is an exclusive licensee of the '203 patent or whether Avadel is an exclusive sublicensee of the '203 patent. Ferring denies the remaining allegations in paragraph 23.

THE '321 PATENT

24. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Ferring admits that the '321 patent issued on August 25, 2009, names Seymour Fein as its sole inventor, is titled "PHARMACEUTICAL COMPOSITIONS INCLUDING LOW DOSAGES OF DESMOPRESSIN," and is listed in the Orange Book as purportedly covering *NOCTIVA*. Ferring also admits that *NOCTIVA* is the subject of approved NDA No. 201656. Ferring denies that '321 patent was duly and legally issued and states that it is invalid and unenforceable. Ferring lacks sufficient information to establish the accuracy of whether Serenity is an exclusive licensee of the '321 patent or whether Avadel is an exclusive sublicensee of the '321 patent. Ferring denies the remaining allegations in paragraph 24.

FACTUAL BACKGROUND

25. Ferring admits that desmopressin is a synthetic analog of the hormone arginine vasopressin and that forms of desmopressin are used to treat a variety of disorders including central diabetes insipidus, nocturnal enuresis, and nocturia. Ferring denies any remaining allegations in paragraph 25.

26. Denied.

27. Denied.

28. Denied.

29. Ferring admits that the Patents in Suit list Dr. Fein as the named inventor. Ferring denies remaining allegations in paragraph 29.

30. Ferring denies that the Patents in Suit embody any inventions of Dr. Fein. On information and belief, Ferring admits that Dr. Fein assigned the Patents in Suit to Reprise. Ferring denies the remaining allegations in paragraph 30.

31. Ferring admits that it filed suit in this District in 2012 and that the case was captioned *Ferring B.V. et al. v. Allergan, Inc. et al*., C.A. No. 12-cv-2650-RWS (S.D.N.Y.). Ferring admits that it alleged, *inter alia*, that the inventorship of the Patents in Suit should be corrected, that the Patents in Suit included "significant inventive contributions" of Ferring's own employees, and sought disgorgement from Serenity and Reprise. Ferring denies any remaining allegations in paragraph 31.

32. Ferring admits that, on April 28, 2017, it filed suit in the District of Delaware alleging that the Patents in Suit are invalid and unenforceable for inequitable conduct. Ferring denies any remaining allegations in paragraph 32.

33. Ferring lacks sufficient information to establish the accuracy of the allegations in this paragraph. Accordingly, Ferring denies the allegations in paragraph 33.

34. Admitted.

SERENITY'S NDA

35. Admitted.

36. On information and belief, Ferring admits that, on March 3, 2017, the FDA approved Serenity's NDA, and *NOCTIVA* became the first drug to be approved for the treatment of nocturia due to nocturnal polyuria in the United States. Ferring denies the remaining allegations in paragraph 36.

FERRING'S NDA

37. Admitted.

38. Ferring admits that it submitted a Pre-Launch Activities Importation Request (PLAIR) on April 24, 2018 requesting that the FDA allow importation of NOCDURNA and that the FDA granted Ferring's PLAIR request on May 3, 2018. Ferring denies the remaining allegations in paragraph 38.

39. Admitted.

40. Ferring admits that June 21, 2018, was the PDUFA (Prescription Drug User Fee Act or expected approval) date for NOCDURNA, that Ferring informed counsel for Serenity and Reprise repeatedly that it expected FDA approval of NOCDURNA in the second quarter 2018, that the letter from FDA to Ferring dated March 2017 (which was produced to Serenity and Reprise) indicated a sea change in FDA's view of desmopressin products for treating nocturia due to nocturnal polyuria, that counsel for Serenity and Reprise chose to ignore the pending approval of NOCDURNA, that counsel for Serenity and Reprise demanded one-sided discovery

but otherwise refused to participate in discovery in this Action, that the FDA approved Ferring's NDA on June 21, 2018, and that Ferring did produce to Serenity and Reprise Ferring's NDA for NOCDURNA in June 2018. Ferring denies the remaining allegations in paragraph 40.

41. Ferring admits that it received from counsel for Serenity and Reprise on June 5, 2018 what purported to be an Order to Show Cause Why A Temporary Restraining Order Should Not Issue. Ferring denies any remaining allegations in paragraph 41.

42. Ferring admits that on June 7, 2018, the parties appeared before the Honorable Robert W. Sweet of the U.S. District Court for the Southern District of New York to discuss, *inter alia*, Serenity and Reprise's TRO Show Cause Application. Ferring denies any remaining allegations in paragraph 42.

43. Ferring admits that it advised Serenity and Reprise that it would not commit to staying off the market until November 2018. Ferring denies any remaining allegations in paragraph 43.

THE NOCTIVA AND NOCDURNA MARKS

44. Ferring avers that the records of the U.S. Patent & Trademark Office ("USPTO") speak for themselves and otherwise admits the allegations of paragraph 44.

45. Ferring avers that the records of the USPTO and the U.S. Food & Drug Administration speak for themselves and otherwise admits the allegations of paragraph 45.

46. Ferring avers that the records of the USPTO speak for themselves and otherwise admits the allegations of paragraph 46.

47. Ferring avers that the records of the USPTO speak for themselves, that the NOCDURNA mark was used in the United States in connection with clinical trials and therefore denies the allegation as to use, and otherwise admits the allegations of paragraph 47.

48. Ferring admits the allegations of paragraph 48.

49. Ferring denies the allegations of paragraph 49.

50. Ferring avers that the records of the Trademark Trial & Appeal Board of the USPTO ("TTAB") speak for themselves and otherwise admits the allegations of paragraph 50.

51. Ferring admits that a case or controversy exists regarding the use of NOCTIVA in view of Ferring's prior rights in NOCDURNA and otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 51.

52. Ferring avers that the records of the TTAB speak for themselves and otherwise admits the allegations of paragraph 52.

53. Ferring admits the allegations of paragraph 53.

54. Ferring B.V. admits that a case or controversy exists regarding the use of NOCTIVA in view of Ferring B.V.'s prior rights in NOCDURNA. Ferring Pharma and FICSA deny that a case or controversy exists as to those entities as they do not own a trademark registration for NOCDURNA. Ferring otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 54.

COUNT I
(INFRINGEMENT OF U.S. PATENT NO. 7,405,203)

55. Ferring incorporates by reference its answers to paragraphs 1 through 54 above as though fully restated herein.

56. Ferring admits that an actual and justiciable case or controversy exists between Counterclaimants and Ferring regarding whether Ferring contributes to the infringement of and/or induces the infringement of one or more claims of the '203 patent. Ferring denies the remaining allegations of paragraph 56.

57. Denied.

58. Ferring denies that the commercial manufacture, use, importation, sale, and/or offer for sale of its NOCDURNA products will contribute to the infringement of and/or induces the infringement of one or more claims of the '203 patent under 35 U.S.C. § 271(b) and § 271(c). Ferring states that it has moved to dismiss Counterclaimants' allegations of infringement under 35 U.S.C. § 271(a) in Count I of Defendants' Counterclaims under Federal Rule of Civil Procedure 12(b)(6) and denies the remaining allegations of paragraph 58.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

63. Denied.

64. Denied.

65. Denied.

66. Denied.

67. Ferring admits that is has been aware of the existence of the '203 patent since at least as early as April 5, 2012, and that it filed the 2012 Action on April 5, 2012. Ferring also admits that the PTO issued Ex Parte Reexamination Certificate No. US 7,405,203 C1 on April 12, 2011. Ferring denies the remaining allegations in paragraph 67.

68. Denied.

69. Denied.

COUNT II
(WILLFUL INFRINGEMENT OF U.S. PATENT NO. 7,405,203)

70. Ferring incorporates by reference its answers to paragraphs 1 through 69 above as though fully restated herein.

71. Ferring admits that is has been aware of the existence of the '203 patent since at least as early as April 5, 2012, and that it filed the 2012 Action on April 5, 2012. Ferring also admits that the PTO issued Ex Parte Reexamination Certificate No. US 7,405,203 C1 on April 12, 2011. Ferring states that the claims of the '203 patent are invalid and unenforceable and denies the remaining allegations in paragraph 71.

72. Denied.

COUNT III
(Infringement of U.S. Patent No. 7,579,321)

73. Ferring incorporates by reference its answers to paragraphs 1 through 72 above as though fully restated herein.

74. Ferring admits that an actual and justiciable case or controversy exists between Counterclaimants and Ferring regarding whether Ferring contributes to the infringement of and/or induces the infringement of one or more claims of the '321 patent. Ferring denies the remaining allegations of paragraph 74.

75. Denied.

76. Ferring denies that the commercial manufacture, use, importation, sale, and/or offer for sale of its NOCDURNA products will infringe, contribute to the infringement of, and/or induces the infringement of one or more claims of the '321 patent under 35 U.S.C. § 271(b) and § 271(c). Ferring states that it has moved to dismiss Counterclaimants' allegations of infringement under 35 U.S.C. § 271(a) in Count III of Defendants' Counterclaims under Federal Rule of Civil Procedure 12(b)(6) and denies the remaining allegations of paragraph 76.

77. Denied.

78. Denied.

79. Denied.

80. Denied.

81. Denied.

82. Denied.

83. Denied.

84. Denied.

85. Denied.

86. Denied.

COUNT IV
(WILLFUL INFRINGEMENT OF U.S. PATENT NO. 7,579,321)

87. Ferring incorporates by reference its answers to paragraphs 1 through 86 above as though fully restated herein.

88. Ferring admits that is has been aware of the existence of the '321 patent since at least as early as April 5, 2012, and that it filed the 2012 Action on April 5, 2012. Ferring denies any remaining allegations in paragraph 88.

89. Denied.

COUNT V
(DECLARATORY JUDGMENT OF NO TRADEMARK INFRINGEMENT)

90. Ferring incorporates by reference its answers to paragraphs 1 through 89 above as though fully restated herein.

91. Ferring admits the allegations of paragraph 91.

92. Ferring B.V. admits the allegations of paragraph 92. Ferring Pharma and FICSA deny that a case or controversy exists as to those entities as they do not own a trademark registration for NOCDURNA.

93. Ferring admits that Serenity seeks the declaration from this Court that its use of the *NOCTIVA* Mark on and in connection with its desmopressin nasal spray does not constitute infringement or unfair competition under the Lanham Act or any other applicable statute or law. Ferring otherwise denies the allegations of paragraph 93.

RESPONSE TO COUNTERCLAIMANTS' PRAYER FOR RELIEF

Ferring denies that Counterclaimants are entitled to any of the relief sought in Counterclaimants' Prayer For Relief set forth in the Answer, Affirmative Defenses, and Counterclaims to Plaintiffs' First Amended Complaint for Declaratory Judgment, and specifically requests that:

(a) Judgment be entered for Ferring denying all relief requested in Counterclaimants' counterclaims, including in paragraphs (A) – (K) in Counterclaimants' Prayer For Relief;

(b) Judgment be entered dismissing Counterclaimants' counterclaims with prejudice;

(c) An award of all allowable costs be assessed against Counterclaimants and awarded to Ferring; and

(d) An award of all such other and further relief the Court deems just and proper be awarded to Ferring.

AFFIRMATIVE DEFENSES

FIRST AFFIMATIVE DEFENSE
(Lack of Standing - Patents)

Counterclaimants' claims for relief are barred in whole or in part due to Counterclaimants' lack of standing to assert claims of infringement of the Patents in Suit.

SECOND AFFIMATIVE DEFENSE
(Invalidity of the Patents in Suit Under 35 U.S.C. §§ 102/103)

The Patents in Suit are invalid under 35 U.S.C. §§ 102/103.

THIRD AFFIMATIVE DEFENSE
(Invalidity of the Patents in Suit Under 35 U.S.C. § 112)

The Patents in Suit are invalid under 35 U.S.C. § 112, including without limitation § 112, ¶¶ 1 and 2.

FOURTH AFFIMATIVE DEFENSE
(The Patents in Suit Are Unenforceable)

The Patents in Suit are unenforceable due to inequitable conduct.

FIFTH AFFIMATIVE DEFENSE
(The Patents in Suit Are Not Infringed)

The commercial manufacture, use, importation, sale, and/or offer for sale of Ferring's NOCDURNA products will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any claim of the Patents in Suit.

SIXTH AFFIMATIVE DEFENSE
(Venue is Improper)

Venue is improper under *TC Heartland LLC v. Kraft Foods Group Brands LLC*, 137 S.Ct. 1514 (2017).

SEVENTH AFFIMATIVE DEFENSE
(Lack of Standing - Trademarks)

Counterclaimants' claims for relief are barred in whole or in part due to Counterclaimants' lack of standing to assert declaratory judgment claims of non-infringement of the NOCDURNA mark by Ferring Pharma and FICSA.

FERRING'S PATENT COUNTERCLAIMS IN REPLY AGAINST AVADEL

For their Counterclaims against Avadel, Ferring hereby alleges as follows:

1. On June 30, 2017, Ferring filed an Amended Complaint (D.I. 18) against, *inter alia*, Defendants Serenity and Reprise seeking a declaration of invalidity and unenforceability of

the patents in suit and a declaration that Ferring's NOCDURNA product does not infringe any claims of the patents in suit. (D.I. 18.)

2. On June 28, 2018, Defendants Serenity and Reprise answered the Amended Complaint and Serenity and Reprise, along with Avadel Specialty Pharmaceuticals, LLC ("Avadel") (collectively with Serenity and Reprise, "Counterclaimants"), filed counterclaims against Ferring, *inter alia*, for infringement of the '203 patent and the '321 patent. (D.I. 101.)

3. Ferring now counterclaims against Avadel, consistent with the allegations against Serenity and Reprise (*see* D.I. 18), seeking a declaration of invalidity and unenforceability of the patents in suit and a declaration that Ferring's NOCDURNA product does not infringe any claims of the '203 patent and the '321 patent).

The Parties

Ferring

4. Plaintiff Ferring Pharmaceuticals Inc. ("Ferring Pharma") is a privately-held Delaware corporation having its principal place of business at 100 Interpace Parkway, Parsippany, New Jersey 07054. Ferring Pharma is owned by Ferring Holding, Inc., which is owned by Ferring B.V.

5. Plaintiff Ferring B.V. is a Dutch private limited liability company having its registered office at Polaris Avenue 144, 2132 JX Hoofddorp, The Netherlands.

6. Plaintiff Ferring International Center S.A. ("FICSA") is a Swiss private limited liability company having its principal place of business at Ch. de la Vergognausaz 50, 1162 Saint-Prex, Switzerland.

Avadel

7. On information and belief, Avadel is organized under the laws of the State of Delaware and has its principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, MO 63005. On information and belief, Avadel is a wholly owned subsidiary of Avadel Pharmaceuticals, plc ("Avadel plc"), a company organized under the laws of Ireland. On information and belief, Avadel sells and offers for sale prescription pharmaceuticals subject to regulations by the U.S. Food and Drug Administration ("FDA").

8. On information and belief, Avadel claims to be an exclusive sublicensee of United States Patent Nos. 7,405,203 ("the '203 patent") and 7,579,321 ("the '321 patent").

9. On information and belief, Avadel claims to be an exclusive sublicensee of the NOCTIVA mark.

Personal Jurisdiction over Avadel

10. This Court has personal jurisdiction over Avadel by virtue of, *inter alia*, the fact that Avadel has agreed not to contest personal jurisdiction or venue in this Court for this action. A true and correct copy of a letter signed by Avadel's Senior Vice President and General Counsel dated January 11, 2017 [sic] (and submitted on January 17, 2018, as Exhibit E to D.I. 63 filed in C.A. No. 17-479-GMS (D.Del.)) details Avadel's consent to personal jurisdiction and venue in this District and is attached here as Exhibit A.

11. This Court also has personal jurisdiction over Avadel by virtue of, *inter alia*, the fact that Avadel has purposely availed itself of the benefits and protections of this Court's laws such that it should reasonably anticipate being haled into court in this District by, *inter alia*, asserting claims for patent infringement in this action.

The Adverse Legal Interests Between the Parties

12. Ferring and Avadel have adverse legal interests to warrant the issuance of a declaratory judgment regarding the invalidity, unenforceability, and non-infringement of the ’203 patent and ’321 patent.

13. There is a substantial controversy between Ferring and Avadel that requires conclusive judicial resolution regarding the invalidity, unenforceability, and non-infringement of the ’203 patent and ’321 patent.

Count I
(Declaratory Judgment of Invalidity of the Patents in Suit Under 35 U.S.C. §§ 102/103)

14. Paragraphs 1 to 13 are incorporated herein as set forth above.

15. Ferring’s decades-long research and development of desmopressin work is extensively documented and shows that (i) PCT ’036 does not cover any purported inventions by Dr. Fein, (ii) relative to the Patents in Suit, PCT ’036 is the work of another, and (iii) Dr. Fein did not make any inventive contribution to the Patents in Suit.

16. The Patents in Suit may claim priority no earlier than May 6, 2003.

17. Under 35 U.S.C. § 102(e), WO ’885 is prior art as of its filing date, September 20, 2002. Therefore, WO ’885 is prior art to PCT ’463 under 35 U.S.C. § 102(e).

18. The claims of each of the Patents in Suit are anticipated by and/or rendered obviousness over WO ’885 in combination with the common knowledge in the art.

19. Dr. Fein did not himself invent the subject matter claimed in the Patents in Suit.

20. The claims of the Patents in Suit are invalid for failure to comply with the conditions for patentability set forth in 35 U.S.C. § 102(f).

Count II
(Declaratory Judgment of Invalidity of the Patents in Suit for Lack of Enablement Under 35 U.S.C. § 112, ¶ 1)

21. Paragraphs 1 to 13 are incorporated herein as set forth above.

22. The specifications of the Patents in Suit fail to enable a person of ordinary skill in the art to make and use the inventions defined by the claims of the Patents in Suit as exemplified in paragraphs 23-28.

23. The specifications of the Patents in Suit fail to enable one of ordinary skill in the art absent undue experimentation to make and administer dosage forms to use in the claimed methods to (i) achieve the claimed plasma/serum concentrations; (ii) deliver claimed amounts of desmopressin to the bloodstream; (iii) treat nocturia, primary nocturnal enuresis, or incontinence; and (iv) achieve the claimed duration of action. (*See, e.g.,* Exhibit C to the Amended Complaint, claims 1 (28:7-14), 10 (28:32-37), 13 (28:45-51).)

24. Further, the specifications of the Patents in Suit also fail to enable one of ordinary skill in the art, absent undue experimentation, to select, make, and/or administer, dosage forms that can achieve a maximum desmopressin plasma/serum concentration no greater than 10 pg/mL by the claimed routes of administration (*i.e.*, transmucosal, transdermal, or intradermal delivery). (*See, e.g.,* Exhibit C to the Amended Complaint, claims 2, 6-8, 10, 13.)

25. The specifications of the Patents in Suit also fail to enable one of ordinary skill in the art to make and administer dosage forms to use in the claimed methods, absent undue experimentation, to achieve the claimed "steady" plasma/serum desmopressin concentration range through intranasal, transdermal, or intradermal administration. (*See, e.g.,* Exhibit E to the Amended Complaint, claims 1-4, 7, 9, 11-17.)

26. The specifications of the Patents in Suit also fail to enable one of ordinary skill in the art to induce voiding postponement in a patient while reducing the risk that the patient develops hyponatremia. (*See, e.g.,* Exhibit D to the Amended Complaint, claims 1-7 and 19-21.)

27. On information and belief, Dr. Fein has admitted that the Patents in Suit are not enabled. For example, on January 22, 2016, Dr. Fein argued that the Patents in Suit failed to address a problem purportedly solved by the subject matter claimed in the '778 Application. (*See* Exhibit N to the Amended Complaint.) Specifically, Dr. Fein argued that the Patents in Suit failed to enable delivery of a low dose of desmopressin to patients to achieve a desmopressin blood concentration sufficient to treat nocturia effectively and safely. (*Id.* at 6.)

28. Dr. Fein submitted a declaration dated June 30, 2016, during prosecution of the '778 Application, in which he stated that (i) the purported inventions claimed in the Patents in Suit demonstrated a need for a low dose desmopressin product for the treatment of nocturia (ii) but that Ferring had not secured FDA approval for a similar invention (*i.e.,* NOCDURNA) and (iii) thus, according to Dr. Fein, there was a long-felt need for a low dose desmopressin product for the treatment of nocturia until the filing of the '778 Application. (*See* Exhibit J to the Amended Complaint at, *e.g.,* 17-20, ¶¶ 7-13.) Moreover, Applicant(s), in response to the Office Action, adopted the arguments in Dr. Fein's declaration. (*Id.* at, *e.g.*, 12.) As the PTO acknowledged, Dr. Fein himself argued that the inventions claimed in the Patents in Suit were not enabled until 2010. (*See* Exhibit O to the Amended Complaint at, *e.g.,* 9, citing Dr. Fein's June 30, 2016, declaration at ¶¶ 7, 13.)

29. The claims of the Patents in Suit are invalid under 35 U.S.C. § 112, ¶ 1 for a lack of enablement.

Count III
(Declaratory Judgment of Invalidity of the Patents in Suit for Inadequate Written Description Under 35 U.S.C. § 112, ¶ 1)

30. Paragraphs 1 to 13 are incorporated herein as set forth above.

31. The specifications of the Patents in Suit fail to provide an adequate written description of the full scope of the claimed inventions as exemplified in paragraph 32 below.

32. The specifications of the Patents in Suit fail to provide an adequate written description to support (i) achieving the claimed plasma/serum concentrations by all claimed routes of administration (*e.g.,* transmucosal, transdermal, intradermal, intravenous, subcutaneous, intranasal) (*see, e.g.,* Exhibit C to the Amended Complaint, claims 1-15; Exhibit D to the Amended Complaint, claims 15-16) or (ii) all indications purportedly treated by the claimed methods (*see, e.g.,* Exhibit C to the Amended Complaint, claims 1-9, 11; Exhibit D to the Amended Complaint, claims 5 and 18).

33. Further, the specifications of the Patents in Suit fail to provide an adequate written description for the same reasons provided in paragraphs 23-28, incorporated fully herein, which shows that Applicants were not in possession of the claimed inventions.

34. The claims of the Patents in Suit are invalid under 35 U.S.C. § 112, ¶ 1 for failing to provide an adequate written description.

Count IV
(Declaratory Judgment of Invalidity of the Patents in Suit Under 35 U.S.C. § 112, ¶ 2)

35. Paragraphs 1 to 13 are incorporated herein as set forth above.

36. The claims of the Patents in Suit are indefinite as exemplified in paragraphs 37-39 below.

37. Claims in the Patents in Suit require transmucosal, transdermal, or intradermal delivery of desmopressin (*see, e.g.,* Exhibit C to the Amended Complaint, claims 2, 6-8, 10, 13)

but these claims fail to particularly point out and distinctly claim the invention. The specification provides no context for "delivery." The limitations claiming transmucosal, transdermal, or intradermal delivery are indefinite.

38. Claims of the Patents in Suit recite a method for inducing voiding postponement in a patient while reducing the risk that the patient develops hyponatremia (*see, e.g.,* Exhibit D to the Amended Complaint, *e.g.*, claim 1-7 and 19-21) but these claims fail to particularly point out and distinctly claim the invention. The specification provides no information on how to measure such risk and how to ascertain if it has been reduced. The limitations claiming a reduction of risk are indefinite.

39. Claims of the Patents in Suit claim a pharmaceutical composition sufficient to establish a steady plasma/serum desmopressin concentration in certain ranges (*see, e.g.,* Exhibit E to the Amended Complaint, claim 5-17) but these claims fail to particularly point out and distinctly claim the invention. The specification provides no context or basis to determine what "steady" means. The limitations claiming a steady plasma/serum desmopressin concentration are indefinite.

40. The claims of the Patents in Suit are invalid under 35 U.S.C. § 112, ¶ 2 for indefiniteness.

Count V
(Declaratory Judgment of Unenforceability of the Patents in Suit)

41. Paragraphs 1 to 13 are incorporated herein as set forth above

42. Dr. Fein made intentional misrepresentations and omissions during the prosecution of the Patents in Suit by, *inter alia*, (i) repeatedly falsely stating under oath that he was the sole inventor of the subject matter claimed in the Patents in Suit, (ii) submitting a false claim of priority for the subject matter claimed in the Patents in Suit, and (iii) failing to disclose

the existence of an inventorship dispute with Ferring over the subject matter claimed in the Patents in Suit. On information and belief, these misrepresentations and omissions were made with the intent to deceive the PTO.

43. Dr. Fein signed a Combined Declaration and Power of Attorney for Sole Inventor ("Combined Declaration") in which he claimed to be the sole inventor of the inventions claimed in the '100 Application. (*See* Exhibit P to the Amended Complaint.) Dr. Fein signed his Combined Declaration on March 19, 2004, acknowledging "the duty to disclose information which is material to patentability in 37 C.F.R. 1.56," and recognizing that any willful false statements "may jeopardize the validity of the application and any patent issuing thereon." (*Id.*)

44. Dr. Fein first submitted his declaration—again, which he signed on March 19, 2004—on March 29, 2004, during prosecution of the application that ultimately issued as the '761 patent (*see* Exhibit P to the Amended Complaint). He submitted it again on July 26, 2007, during prosecution of the application that ultimately issued as the '203 patent (*see* Exhibit Q to the Amended Complaint), and submitted it again on July 15, 2008, during prosecution of the application that ultimately issued as the '321 patent (*see* Exhibit R to the Amended Complaint).

45. At the times Dr. Fein signed and submitted his Combined Declaration, he knew that (i) he was not the sole inventor of the subject matter claimed in the Patents in Suit, (ii) his claim of priority for the subject matter claimed in the Patents in Suit was false, and (iii) his claim to sole inventorship of the subject matter claimed in the Patents in Suit was disputed by Ferring.

46. A central example in the Patents in Suit is Example 8, which describes a clinical study designed to evaluate the "antidiuretic effect of three low doses of desmopressin administered via intravenous infusion for 2 hours in over-hydrated, healthy, non-smoking male and female volunteers." (Exhibit C to the Amended Complaint at col. 20:39-42.) Dr. Fein did not

conceive of Example 8; Example 8 is essentially a copy of a Ferring clinical study protocol for a Ferring clinical study called CS009. A simple comparison of the Ferring CS009 clinical study protocol to Example 8 demonstrates that (i) both have the same primary objective, (ii) the methodologies used are essentially the same, including relatively small number of subjects healthy, overhydrated, non-smoking male and female volunteers with ascending similar low doses, (iii) both use the same route of administration, i.v., (iv) both have the same duration of treatment, and (v) both evaluate the same endpoints. Therefore, Dr. Fein knew that Example 8 was conceived of and reduced to practice by Ferring. The inventions claimed in the Patents in Suit rely on Example 8 for patentability. For example, the specification itself relies on Example 8 as justification for the claimed doses and concentrations for various routes of administration. (*See* Exhibit C to the Amended Complaint at col. 25:63-65, 26:63-27:3; *see also id.* at 27:48-51 (stating that Example 8 "demonstrates that desmopressin can produce this essential antidiuretic effect at much lower doses and lower blood concentrations than previously thought")) *see also, e.g.*, Exhibit S to the Amended Complaint, at 16 of 22 (referring the Examiner to Example 8 for disclosure of "administration to achieve a desmopressin blood concentration within the range claimed and show[ing] specifically the antidiuretic effect"); Exhibit T to the Amended Complaint at 6 of 7 (stating that support of the claimed subject matter can be found, *inter alia*, in Example 8 "for subject matter of *antidiuretic effect*"); Exhibit U to the Amended Complaint at 3 (stating that "[f]rom these studies [Example 8], it was established that the threshold desmopressin blood concentration sufficient to produce an anti-diuresis effect was much lower than the concentrations typically achieved in prior art practice").

47. Example 8 was not included in the priority application, GB '397, or even PCT '463. In fact, Example 8 was not added to the specification of any document in the chain of

priority for the patents in suit until November 12, 2003, when Dr. Fein filed the '100 Application. Dr. Fein was aware that Example 8 was crucial for patentability of the patents in suit and that it was not included until November 2003. Dr. Fein deliberately provided the PTO with an improper priority claim during prosecution of the Patents in Suit. For example, in Dr. Fein's sworn Combined Declaration, Dr. Fein claimed foreign priority benefits under 35 U.S.C. § 119 to GB '397. Dr. Fein knew the priority claim was false. On information and belief, Dr. Fein claimed priority to GB '397 with an intent to deceive the PTO.

48. Dr. Fein knew that there was an inventorship dispute with Ferring, at least over Example 8, which was conceived by others but crucial to the patentability of the patents in suit, and made a deliberate decision to withhold the dispute from the PTO. The single most reasonable inference is that Dr. Fein had the specific intent to deceive the PTO.

49. During prosecution, examiners are required to consider the requirements of all sections of 35 U.S.C., including § 102(f). Dr. Fein had a duty to disclose material information related to patentability, which includes information related to inventorship conflicts. *See, e.g., Manual Patent Examining Procedure*, § 2001.04. The duty of disclosure under 37 C.F.R. § 1.56 applies to all dealings with the PTO, including prosecution of the applications that ultimately issued as the Patents in Suit, which includes prosecution through issuance and the reexamination of the '203 patent.

50. Dr. Fein breached or otherwise failed to satisfy his duty to disclose material information and breached or otherwise failed to satisfy his duty of candor before the PTO during prosecution of the Patents in Suit by, *inter alia*, submitting misleading, improper, and/or false claims of inventorship and/or priority, and/or failing to disclose material information. On

information and belief, Dr. Fein acted with an intent to deceive the PTO during prosecution of the Patents in Suit.

Count VI
(Declaratory Judgment of Noninfringement of the '203 Patent and the '321 Patent)

51. Paragraphs 1 to 13 are incorporated herein as set forth above.

52. An actual and justiciable case or controversy exists between Ferring and Avadel regarding whether the use of Ferring's NOCDURNA will infringe the claims of the '203 patent and the '321 patent.

53. The use of Ferring's NOCDURNA will not infringe any valid claim of the '203 patent and the '321 patent as properly construed.

54. Ferring will not directly or indirectly (*e.g.,* by inducement) infringe any valid claim of the '203 patent and the '321 patent as properly construed.

Prayer for Relief

WHEREFORE, Ferring respectfully requests the following judgment and relief:

(a) A declaration be issued under 28 U.S.C. § 2201 that the claims of the '203 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 102(e), 102(f), 112, ¶ 1, and 112, ¶ 2;

(b) A declaration be issued under 28 U.S.C. § 2201 that the '203 patent is unenforceable due to inequitable conduct during prosecution of the application that issued as the '203 patent and/or during reexamination of the '203 patent;

(c) A declaration be issued that Ferring's NOCDURNA does not infringe any claim of the '203 patent;

(d) That an injunction be issued enjoining Avadel and its agents, representatives, attorneys, employees, and those persons in active concert or participation with them who receive actual notice herefrom from threatening or initiating infringement litigation against Ferring or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors or customers of Ferring, or charging them either orally or in writing with infringement of the '203 patent;

(e) A declaration be issued under 28 U.S.C. § 2201 that the claims of the '321 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 102(e), 102(f), 112, ¶ 1, and 112, ¶ 2;

(f) A declaration be issued under 28 U.S.C. § 2201 that the '321 patent is unenforceable due to inequitable conduct during prosecution of the application that issued as the '321 patent;

(g) A declaration be issued that Ferring's NOCDURNA does not infringe any claim of the '321 patent;

(h) That an injunction be issued enjoining Avadel and its agents, representatives, attorneys, employees, and those persons in active concert or participation with them who receive actual notice herefrom from threatening or initiating infringement litigation against Ferring or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors or customers of Ferring, or charging them either orally or in writing with infringement of the '321 patent;

(i) A declaration be issued under 28 U.S.C. § 2201 that the claims of the '761 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in

Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 102(e), 102(f), 112, ¶ 1, and 112, ¶ 2;

(j) A declaration be issued under 28 U.S.C. § 2201 that the '761 patent is unenforceable due to inequitable conduct during prosecution of the application that issued as the '761 patent and/or during reexamination of the '761 patent;

(k) A declaration be issued that Ferring's NOCDURNA does not infringe any claim of the '761 patent;

(l) That an injunction be issued enjoining Avadel and its agents, representatives, attorneys, employees, and those persons in active concert or participation with them who receive actual notice herefrom from threatening or initiating infringement litigation against Ferring or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors or customers of Ferring, or charging them either orally or in writing with infringement of the '761 patent;

(m) A judgment and order that this is an exceptional case under 35 U.S.C. § 285 and awarding Ferring its reasonable attorneys' fees, costs, and expenses; and

(n) Any and all other and further relief as this Court deems just and proper.

FERRING B.V.'S TRADEMARK COUNTERCLAIMS IN REPLY AGAINST COUNTERCLAIMANTS

For their Counterclaim against Defendants Serenity Pharmaceuticals, LLC, Reprise Biopharmaceuticals, LLC and Avadel Specialty Pharmaceuticals, LLC (collectively, "Defendants"), Plaintiff Ferring B.V. ("Ferring B.V.") hereby alleges as follows:

1. On June 30, 2017, Ferring filed an Amended Complaint (D.I. 18) against, *inter alia*, Defendants Serenity and Reprise seeking a declaration of invalidity and unenforceability of

the patents in suit and a declaration that Ferring's NOCDURNA product does not infringe any claims of the patents in suit. (D.I. 18.)

2. On June 28, 2018, Defendants Serenity and Reprise answered the Amended Complaint and Serenity and Reprise, along with Avadel Specialty Pharmaceuticals, LLC ("Avadel") (collectively with Serenity and Reprise, "Counterclaimants"), filed counterclaims against Ferring, *inter alia*, seeking a declaration of no trademark infringement. (D.I. 101.)

3. Ferring B.V. now counterclaims in reply against Counterclaimants, consistent with the allegations against Serenity and Reprise (*see* D.I. 18) and Avadel (above), for federal trademark infringement.

4. Plaintiff Ferring B.V., thorough its affiliated entities (collectively, "Ferring") is a leading producer of pharmaceuticals. Since 2016, Ferring has offered a pharmaceutical under the brand name NOCDURNA outside of the United States directed to the treatment of nocturia, a condition associated with excessive urination during the night. Pursuant to protections afforded under the Trademark Act of 1946 (the "Lanham Act") to the owners of foreign trademarks with the intent to use such marks in the United States, in September 2013, Plaintiff Ferring B.V. registered its NOCDURNA mark with the U.S. Patent & Trademark Office ("USPTO") based on the impending approval of the drug for sale in the United States, which such approval issued on June 21, 2018.

5. Despite the renown of the NOCDURNA mark and despite having actual and constructive knowledge of Plaintiff Ferring B.V.'s rights therein, and despite the fact that Plaintiff Ferring B.V. and Counterclaimants' predecessor Allergan, Inc. were in the midst of an administrative litigation at the Trademark Trial and Appeal Board of the USPTO ("TTAB"), Counterclaimants have, without authorization or permission from Plaintiff Ferring B.V., chosen

NOCTIVA for their own pharmaceutical for the treatment of nocturia and are marketing and selling such pharmaceutical throughout the United States, including but not limited to in this district. Such use of NOCTIVA, which is highly similar to NOCDURNA, impermissibly creates an association between Plaintiff Ferring B.V. and Counterclaimants in the minds of consumers when no such association exists.

6. As a result, to protect the goodwill that it has established in the NOCDURNA mark, Plaintiff Ferring B.V. brings this action for trademark infringement under Section 32(1) of the Lanham Act, 15 U.S.C. § 1114(1). As described below, Plaintiff Ferring B.V. seeks injunctive relief, an accounting of any' profits flowing from Counterclaimants use of NOCTIVA, damages, attorneys' fees, and such other relief as the Court deems just and proper.

The Parties

7. Plaintiff Ferring B.V. is a Dutch private limited liability company having its registered office at Polaris Avenue 144, 2132 JX Hoofddorp, The Netherlands.

8. On information and belief, Defendant Serenity Pharmaceuticals, LLC, ("Serenity") is organized under the laws of the State of Delaware, and has its principal place of business at 105 Hawk Court, Milford, Pennsylvania, 18337. On information and belief, Serenity also maintains an address at 120 North Main Street, Suite 400, New City, New York 10956.

9. On information and belief, Defendant Reprise Biopharmaceutics, LLC ("Reprise") is organized under the laws of the State of New York, and has its principal place of business at 120 North Main Street, Suite 400, New City, New York, 10956.

10. On information and belief, Avadel Specialty Pharmaceuticals, LLC ("Avadel") is a limited liability company organized and existing under the laws of Delaware, with its principal place of business located at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, MO 63005.

Jurisdiction and Venue

11. This Court has jurisdiction over the subject matter of this action pursuant to Section 39 of the Lanham Act, 15 U.S.C. § 1121, and under Sections 1331, 1338(a) and 1338(b) of the Judicial Code, 28 U.S.C. §§ 1331, 1338(a) and 1338(b).

12. This Court has personal jurisdiction over Counterclaimants because, *inter alia*, Counterclaimants have purposely availed themselves of the benefits and protections of this Court's laws such that they should reasonably anticipate being haled into court in this District by, *inter alia*, asserting claims for patent infringement and seeking a declaratory judgment of no trademark infringement in this action.

13. This Court has personal jurisdiction over Counterclaimants under Sections 301 and/or 302 of the New York Civil Practice Laws and Rules because, upon information and belief, (i) Counterclaimants continuously and systematically conduct, transact and solicit business in the State of New York, (ii) Counterclaimants have committed and is committing tortious acts within this State by marketing, promoting, advertising and offering for sale the products bearing the infringing trademark and (iii) the events giving rise to this Counterclaim occurred in the State of New York and/or had effects in this State.

14. Venue is proper in this district pursuant to Sections 1391(b) and (c) of the Judicial Code, 28 U.S.C. §§ 1391(b) and (c), in that a substantial part of the events giving rise to the claims, including, but not limited to, Counterclaimants' marketing, promoting, advertising, and offering for sale of pharmaceuticals in violation of Plaintiff Ferring B.V.'s exclusive rights in the NOCDURNA mark occurred in this District, Plaintiff Ferring B.V. is suffering harm in this District, and Counterclaimants are subject to personal jurisdiction in this District.

Facts Common to the Counterclaims For Relief Against Counterclaimants

Ferring and the NOCDURNA Mark

15. Ferring has for many years been engaged in the manufacture, distribution, marketing and sale of pharmaceutical products.

16. In 2009, Ferring submitted an application for a New Drug Application ("NDA") to the U.S. Food & Drug Administration ("FDA") for a new treatment for nocturia under the proposed trademark NOCDURNA.

17. Simultaneously, Plaintiff Ferring B.V. on August 7, 2009 filed an application to register NOCDURNA in the USPTO. That application matured into U.S. federal trademark Reg. No. 4,405,021 for "pharmaceutical products and preparations for use in treating urological disorders and conditions" in International Class 5, based on Section 44(e) of the Lanham Act, 15 U.S.C. § 1126(e), registered on July 9, 2013. This registration is valid, subsisting and in full effect and serves as prima facie evidence of the validity of the NOCDURNA mark, pursuant to Section 33(a) of the Lanham Act, 15 U.S.C. § 1115(a).

18. On June 21, 2018, the FDA approved NOCDURNA for sale in the United States.

19. Promptly thereafter, Ferring launched a website at http://www.nocdurna.com to educate the public about NOCDURNA, in anticipation of sales beginning in the second half of 2018.

Counterclaimants' Wrongful Activities

20. In February 2016, Serenity submitted an NDA to the FDA for its own new nocturia treatment.

21. Upon information and belief, Serenity and its former business partner Allergan, Inc., considered a number of trademarks for the name of this new product. According to the

records of the USPTO, Serenity owns a number of pending trademark applications filed by Allergan on an intent-to-use basis (and subsequently assigned to Serenity) for pharmaceutical products directed to treat nocturia: REMIO, NOZURIA, RELISERA, REMNOCT, PAZINOCT, RESTNOCT, PACSERA, NOCUVANT, NOCTRISA and NOCTIVA.

22. The application to register NOCTIVA was filed in April 2014, nearly five years after Plaintiff Ferring B.V. first filed its trademark application for NOCDURNA and nearly a year after that application matured to registration.

23. Notwithstanding its prior constructive notice that Ferring's nocturia treatment was named NOCDURNA, Serenity chose NOCTIVA, the closest of all available options to NOCDURNA in sight, sound and commercial impression.

24. In October 2014, counsel for Ferring sent a cease and desist letter to counsel for Allergan (who was then the owner of record of the NOCTIVA trademark application) objecting to the intended use of NOCTIVA in connection with a nocturia pharmaceutical treatment.

25. Upon Allergan's refusal to abandon its application and intended use, Plaintiff Ferring B.V. commenced an opposition to the registration of NOCTIVA (as well as NOCUVANT and NOCTRISA) in the TTAB, Opp. Nos. 91219485, 91219486 and 91219487 (the "Oppositions").

26. The FDA approved Serenity's application for its nocturia treatment in March 2017 under the NOCTIVA trademark.

27. In April 2018, Counterclaimants launched NOCTIVA.

28. Counterclaimants are not associated or affiliated with Plaintiff Ferring B.V.

29. The pharmaceutical product to treat nocturia Counterclaimants offer under NOCTIVA is not offered or approved by Plaintiff Ferring B.V.

30. NOCDURNA and NOCTIVA have highly similar commercial impressions, sharing the same NOC- prefix and ending in –A. Moreover, the "T" in NOCTIVA is easy to pronounce as a "D", further connecting the two names.

31. Although NOCDURNA (a tablet) and NOCTIVA (a nasal spray) work differently, they are products each containing desmopressin acetate as the active ingredient and each approved to treat the same medical condition, nocturia due to nocturnal polyuria.

32. Counterclaimants' use of NOCTIVA in connection with a pharmaceutical product to treat nocturia due to nocturnal polyuria began nearly five years after Plaintiff Ferring B.V. first secured its federal trademark registration for the NOCDURNA mark in connection with a pharmaceutical product to treat nocturia.

33. Furthermore, Counterclaimants, by virtue of, *inter alia*, Plaintiff Ferring B.V.'s demand letter and the Oppositions, were on actual notice of Plaintiff's rights in the NOCDURNA mark long before Defendants adopted NOCTIVA.

34. Accordingly, Counterclaimants' unauthorized use of NOCTIVA is with a deliberate intent to trade on the goodwill of Plaintiff Ferring B.V.'s NOCDURNA mark and with the deliberate intent to create a false impression as to the source or sponsorship of Counterclaimants' pharmaceutical product to treat nocturia. The goodwill that Plaintiff Ferring B.V. has built up in its NOCDURNA mark through years of substantial investment and effort is put at risk by virtue of Counterclaimants' misappropriation of the NOCDURNA mark to sell and promote its own pharmaceutical product to treat nocturia due to nocturnal polyuria.

35. Counterclaimants' acts are likely to injure Plaintiff Ferring B.V.'s goodwill and reputation. The use by Counterclaimants of Plaintiff Ferring B.V.'s NOCDURNA mark unfairly and unlawfully wrests from Plaintiff Ferring B.V. control over its valuable trademarks and

reputation. Plaintiff Ferring B.V. has no control over the quality of Counterclaimants' pharmaceutical product to treat nocturia due to nocturnal polyuria. As a result, Counterclaimants' use of NOCTIVA jeopardizes and may permanently damage Plaintiff Ferring B.V.'s extremely valuable reputation.

36. Thus, Counterclaimants' unauthorized acts as described herein have caused and will continue to cause irreparable damage to Plaintiff Ferring B.V.'s business and goodwill unless restrained by this Court.

COUNTERCLAIM FOR RELIEF
(Federal Trademark Infringement Under 15 U.S.C. § 1114(1))

37. Plaintiff Ferring B.V. repeats and realleges the allegations set forth in Paragraphs 1 through 36 as if fully set forth herein as set forth above.

38. Counterclaimants' advertising, promotion, offering for sale and sale of pharmaceutical products to treat nocturia due to nocturnal polyuria under the name NOCTIVA is likely to cause confusion, mistake or deception as to the source or sponsorship of Counterclaimants' goods.

39. As a result of Counterclaimants' use of NOCTIVA and in view of Plaintiff Ferring B.V.'s prior rights in NOCDURNA, consumers are likely to believe that Counterclaimants' pharmaceutical products to treat nocturia due to nocturnal polyuria have been approved by or are otherwise associated with Plaintiff Ferring B.V.

40. Such use falsely represents Counterclaimants as being legitimately connected with and/or authorized by Plaintiff Ferring B.V. and places beyond Plaintiff Ferring B.V.'s control its own reputation and ability to control the use of the NOCDURNA mark or the quality of the goods bearing those marks.

41. Counterclaimants' infringement of Plaintiff Ferring B.V.'s registered trademark is willful, intended to reap the benefit of the goodwill of Plaintiff Ferring B.V., and violates Section 32(1) of the Lanham Act, 15 U.S.C. § 1114(1).

42. Counterclaimants' conduct has caused and is causing irreparable injury to Plaintiff Ferring B.V. and will continue to both damage Plaintiff Ferring B.V. and deceive the public unless enjoined by this Court.

43. Plaintiff Ferring B.V. has no other adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Ferring B.V. respectfully requests the following judgment and relief:

(a) That a permanent injunction be issued enjoining Counterclaimants, and any of their officers, agents, privies, shareholders, principals, directors, licensees, attorneys, servants, employees, affiliates, subsidiaries, successors and assigns, and all those persons in concert or participation with any of them, and any entity owned or controlled in whole or in part by any of Counterclaimants, in any jurisdiction in which they operate, from:

(i) imitating, copying or making unauthorized use of the NOCDURNA mark, or any simulation, reproduction, copy, colorable imitation or confusingly similar variation thereof, including but not limited to NOCTIVA (any such mark, a "Prohibited Mark"), in or as part of any corporate name, trademark, service mark, domain name, trade name, business name, fictitious name, or otherwise presenting any name that includes in whole or in part a Prohibited Mark on or in connection with any goods, businesses or services offered by Counterclaimants or the advertising or promotion thereof;

(ii) using a Prohibited Mark to refer to or describe any products, goods or services offered by or on behalf of Counterclaimants or any individual, entity or other third party affiliated with Counterclaimants;

(iii) using a Prohibited Mark in or as part of any domain name, keyword, metatag, source code or other Internet search term, or otherwise using a Prohibited Mark on or in connection with any website owned or controlled by Counterclaimants;

(iv) applying to register or registering in the United States Patent and Trademark Office, or in any state trademark registry, any Prohibited Mark;

(v) using a Prohibited Mark in connection with the promotion, advertisement, sale, offering for sale or the provision of any goods or services;

(vi) engaging in any other activity constituting an infringement of Plaintiff Ferring B.V.'s NOCDURNA mark; or

(vii) instructing, assisting, aiding or abetting any other person or entity in engaging in or performing any of the activities referred to in subparagraphs (i) through (vi) above.

(b) Directing that Counterclaimants deliver up to Plaintiff Ferring B.V. for destruction all goods, labels, tags, signs, stationery, prints, packages, promotional and marketing materials, advertisements and other materials currently in their possession or under their control, incorporating, featuring or bearing any Prohibited Mark.

(c) Directing that Counterclaimants disable and transfer to Plaintiff Ferring B.V. any domain name incorporating a Prohibited Mark.

(d) Directing such other relief as the Court may deem appropriate to prevent the public from deriving the erroneous impression that any good offered or promoted by Counterclaimants within the United States is authorized by Plaintiff Ferring B.V. or related in any way to Plaintiff Ferring B.V. or that Counterclaimants are otherwise affiliated with Plaintiff Ferring B.V.

(e) Directing that Counterclaimants file with the Court and serve upon Plaintiff Ferring B.V.'s counsel within thirty (30) days after entry of judgment a report in writing under oath, setting forth in detail the manner and form in which it has complied with the above.

(f) Awarding Plaintiff Ferring B.V. such damages it has sustained or will sustain by reason of Counterclaimants' acts of trademark infringement.

(g) Awarding Plaintiff Ferring B.V. all gains, profits, property and advantages derived by Counterclaimants from its unlawful conduct and, pursuant to 15 U.S.C. § 1117, awarding Plaintiff Ferring B.V. an amount up to three times the amount of actual damages sustained as a result of Counterclaimants' violation of the Lanham Act.

(h) Awarding to Plaintiff Ferring B.V. exemplary and punitive damages to deter any further willful trademark infringement as the Court finds appropriate.

(i) Awarding to Plaintiff Ferring B.V. its costs and disbursements incurred in this action, including reasonable attorneys' fees.

(j) Awarding to Plaintiff Ferring B.V. interest, including pre-judgment interest on the foregoing sums.

(k) Awarding to Plaintiff Ferring B.V. such other interim relief, including, but not limited to a preliminary injunction, or permanent relief as the Court may deem just and proper.

Dated: July 19, 2018

GIBBONS P.C.

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